

# EXHIBIT C

Duane Priddy, Ph.D.

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UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC )  
REPAIR SYSTEM PRODUCTS ) Master File No.  
LIABILITY LITIGATION ) 2:12-MD-02327  
THIS DOCUMENT RELATES TO THE ) MDL 2327  
FOLLOWING CASES IN WAVE 1 OF ) JOSEPH R. GOODWIN  
OF MDL 200: ) U.S. DISTRICT JUDGE  
-----)  
HARRIET BEACH )  
v. ) CIVIL ACTION FILE  
 ) No. 2:12-CV-00476  
ETHICON, INC., et al. )  
-----)  
SHARON BOGGS, et al. )  
 ) CIVIL ACTION FILE  
v. ) No. 2:12-CV-00368  
 )  
ETHICON, INC., et al. )  
-----)  
JUDITH BRUHN, et al. )  
 ) CIVIL ACTION FILE  
v. ) No. 2:12-CV-00888  
 )  
ETHICON, INC., et al. )  
-----)  
JANICE COLONNA )  
 ) CIVIL ACTION FILE  
v. ) No. 2:12-CV-01274  
 )  
ETHICON, INC., et al. )  
-----)  
MARY F. CONE )  
 ) CIVIL ACTION FILE  
v. ) No. 2:12-CV-00261  
 )  
ETHICON, INC., et al. )  
-----)  
SANDRA CYRUS ) CIVIL ACTION FILE  
v. ) No. 2:12-CV-01283  
ETHICON, INC., et al. )  
-----)

Videotaped Deposition of DUANE PRIDDY, PH.D.  
March 8, 2016

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1 MR. JACKSON: Objection, calls for a  
2 legal conclusion.

3 A. Let's put it this way: I don't advertise  
4 myself as an expert for FDA.

5 BY MR. HUTCHINSON:

6 Q. Is there anything on your CV that reflects  
7 your expertise as a regulatory or FDA expert?

8 A. No.

9 Q. Doctor, you are not a pathologist?

10 A. I am not a pathologist.

11 Q. Not a medical doctor?

12 A. I am not a medical doctor.

13 Q. Not a toxicologist?

14 A. No.

15 Q. Not a biostatistician?

16 A. What?

17 Q. A biostatistician?

18 A. A biostatistician, I do a lot of  
19 statistical analysis, but bio, not a  
20 biostatistician.

21 Q. Are you an epidemiologist?

22 A. No, I'm not.

23 Q. Are you an expert in biomaterials?

24 MR. JACKSON: Objection, form.

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1 Q. But 2014 -- or 14, rather, stands for  
2 the year, correct?

3 A. Correct.

4 Q. You used an older version of the ASTM  
5 3895?

6 MR. JACKSON: Objection, form.

7 A. Yes.

8 BY MR. HUTCHINSON:

9 Q. Why?

10 A. Because I have been doing it for many  
11 years preceding '14, and once I get the lab set up  
12 doing a specific test, following a specific standard  
13 in a specific way, I just don't deviate it.

14 Q. Sir, did you ever compare the version, the  
15 older version that you used of 3895 to the most  
16 recent ASTM 3895 2014?

17 A. No.

18 Q. Are you aware of any changes between those  
19 two ASTM protocols?

20 A. I would have to study it in depth to look  
21 for those differences.

22 Q. But you can't tell us those differences  
23 now?

24 A. No.

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1 BY MR. HUTCHINSON:

2 Q. So all products that you received had mesh  
3 between two stainless steel rods; is that correct?

4 A. That's my recollection, yes.

5 Q. Doctor, let's talk about the sampling that  
6 was used for the DSC. DSC is a test, by the way,  
7 right?

8 A. Yes.

9 Q. That's an analytical test?

10 A. It's a piece of equipment.

11 Q. And the purpose of the equipment is in  
12 essence to melt the product inside, fair enough?

13 MR. JACKSON: Objection, form.

14 A. No.

15 BY MR. HUTCHINSON:

16 Q. What's the purpose of the equipment?

17 A. It's to detect thermal heat flow, whether  
18 it be cooling or heating with plastic materials.

19 Q. But you do that by melting the plastic  
20 material, correct?

21 MR. JACKSON: Objection, form.

22 A. Not necessarily.

23 BY MR. HUTCHINSON:

24 Q. Did you melt the samples that you received



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1 in this case?

2 A. At 200 degrees, that's above the melting  
3 point so they would be melted, yes.

4 Q. How did you make the specimen sample?

5 A. It was cut with scissors.

6 Q. In your lab or in Steve Johnson's lab?

7 A. Steve Johnson did the cutting.

8 Q. Were you supervising the cutting of the  
9 samples with Steve Johnson?

10 A. I was not present, but we discussed the  
11 protocol of how to collect the samples.

12 Q. What was the average sheet thickness of  
13 the sample?

14 MR. JACKSON: Objection, form.

15 A. I don't recall.

16 BY MR. HUTCHINSON:

17 Q. Did you ever ask Steve Johnson about what  
18 the average sheet thickness was of the sample?

19 A. I asked him what the thickness was.

20 Q. What did he tell you?

21 A. I don't recall. It was less than -- I  
22 don't recall.

23 Q. Why is that not included in your expert  
24 report?

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1           A.     Because it wasn't relevant to my opinion.

2           Q.     Doctor, was this test sample compressed or  
3     molded into a sheet format?

4           A.     No.

5           Q.     Why not?

6           A.     Because that would have given the sample  
7     another heat history, and I wanted to have the  
8     samples tested in their original use shape as  
9     monofilaments.

10          Q.     How many times was the DSC test run?

11                 MR. JACKSON: Objection, form.

12          A.     It's run once, and I had him run it in  
13     pure oxygen, switching from nitrogen to oxygen, and  
14     I also asked him to run it switching from nitrogen  
15     to air, so he ran it twice for each sample.

16     BY MR. HUTCHINSON:

17          Q.     Do you know how long he ran it in pure  
18     nitrogen?

19          A.     You run it for so many minutes until the  
20     equipment is stable, get a smooth baseline. That's  
21     generally five minutes or so at 200.

22          Q.     But my question is, do you know how long  
23     Steve Johnson ran it in pure nitrogen?

24          A.     Whatever the standard dictates, and I

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1 believe it's five minutes.

2 Q. Do you know how long Steve Johnson ran the  
3 sample or ran the test, rather, in pure oxygen?

4 MR. JACKSON: Objection, asked and  
5 answered.

6 A. It's in the data. Once you switch from  
7 nitrogen to oxygen, that's time 0, and then you run  
8 it in pure oxygen until the exotherm is over and  
9 that gives you your OIT data.

10 BY MR. HUTCHINSON:

11 Q. Let's look at Exhibit 4 and turn with me  
12 to Page 2.

13 A. Okay.

14 Q. Under "9. sampling." Do you see that?

15 A. Yes.

16 Q. 9.1 says, "The following sample  
17 preparation procedures are recommended: the test  
18 sample is compression molded into sheet format."

19 Did I read that correctly?

20 A. Absolutely.

21 Q. Why did you not follow that protocol?

22 MR. JACKSON: Objection, form.

23 A. Because it's recommended and, as I said  
24 previously, that would require another heat history



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1 on the sample, and I wanted to look at pristine mesh  
2 samples in their use state. And I didn't want to  
3 alter that.

4 So that would have affected the results to  
5 have done it that way. And I emphasize the word  
6 "recommended," because you don't have to do it that  
7 way, it's just the recommended.

8 Q. I understand, but fair to say that you  
9 didn't follow the recommended sampling procedure in  
10 ASTM 3895, correct?

11 MR. JACKSON: Objection, form.

12 A. Absolutely for good reason, it would have  
13 affected the results negatively.

14 BY MR. HUTCHINSON:

15 Q. Doctor, there is nothing in your expert  
16 report about how the samples were prepared, is  
17 there?

18 A. Not in the report directly, no.

19 Q. Why did you not include that in your  
20 expert report?

21 A. Because it has no bearing on my opinions.

22 Q. Doctor, did you do any type of statistical  
23 calculations to confirm that the results you got  
24 from this test that Steve Johnson did were

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1 statistically significant?

2 MR. JACKSON: Objection, form.

3 A. What I did do --

4 BY MR. HUTCHINSON:

5 Q. We are going to get to what you did do in  
6 a minute. I want to know the answer to my question  
7 first and then we'll get there.

8 MR. JACKSON: Counsel, you have to  
9 let him answer the question.

10 BY MR. HUTCHINSON:

11 Q. Did you do any type of statistical  
12 calculations to --

13 A. Yes.

14 Q. Are those statistical calculations  
15 included in your expert report?

16 A. No.

17 Q. Why not?

18 A. Just didn't include it.

19 Q. Any reason?

20 A. No.

21 Q. What type of statistical calculations did  
22 you do?

23 A. I had Steve Johnson extract the additives  
24 from the mesh samples and to determine if the OIT

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1 numbers data gave a correlation with the level of  
2 antioxidant in the mesh samples. And the reason I  
3 did that is just to confirm that there's a  
4 statistical correlation between the level of  
5 antioxidant and the OIT values because if there  
6 hadn't have been, then I would have been concerned  
7 about the validity of the results.

8 Q. Doctor, let's look at Exhibit 4 for a  
9 minute. This is that ASTM 3895.

10 A. Yes.

11 Q. Bottom of Page 1, 4.3 states, "Unless  
12 otherwise specified, the analysis temperature used  
13 in this test has been arbitrarily set at 200 degrees  
14 C."

15 Do you see that?

16 A. Yes.

17 Q. That's the temperature you used?

18 A. Correct.

19 Q. You used an arbitrary number?

20 MR. JACKSON: Objection, form.

21 A. I used the number specified in the  
22 standard, yes.

23 BY MR. HUTCHINSON:

24 Q. And the number specified in the standard

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1           A.    If it is specified in the standard, yes.

2   BY MR. HUTCHINSON:

3           Q.    Doctor, your report states that the mesh  
4   sample was heated to 200 degrees under pure  
5   nitrogen; is that right?

6           A.    Yes.

7           Q.    That's the temperature at which you  
8   conducted this aging study?

9           MR. JACKSON:  Objection, form.

10          A.    Correct.

11   BY MR. HUTCHINSON:

12          Q.    That's also known as the accelerated aging  
13   temperature, correct?

14          A.    Yes.

15          Q.    That equates to roughly 392 degrees  
16   Fahrenheit?

17          A.    Correct.

18          Q.    That's about 300 degrees Fahrenheit above  
19   the normal temperature of a human being; is that  
20   correct?

21          A.    Correct.

22          Q.    And it is well above the melting point of  
23   Prolene, isn't it?

24          MR. JACKSON:  Objection, form.



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1           A.    Yes, it is.

2   BY MR. HUTCHINSON:

3           Q.    What is the melting point of Prolene?

4           A.    165 degrees Centigrade approximately.

5           Q.    Doctor, moving to Page 2, at the top under  
6   Significance and Use, are you there with me?

7           A.    Yes.

8           Q.    It says, "The OIT is a qualitative  
9   assessment of the level (or degree) of stabilization  
10   of the material tested."

11                   Do you see that?

12          A.    Yes.

13          Q.    And a qualitative test is different from a  
14   quantitative test, isn't it, sir?

15          A.    That's correct.

16          Q.    A qualitative test doesn't give you a  
17   lifetime prediction, does it?

18                   MR. JACKSON:  Objection, form.

19   BY MR. HUTCHINSON:

20          Q.    Doctor?

21          A.    It's standard practice to use data from  
22   these kind of tests to do lifetime predictions,  
23   realizing it's only a prediction.  With that  
24   understanding that it has to be validated by actual



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1 testing. If there's a red flag there, it will just  
2 give you a red flag. And so with that  
3 understanding, as I say, I routinely use this test  
4 for doing lifetime predictions.

5 Q. I understand, but with that understanding,  
6 a qualitative test does not give you lifetime  
7 predictions, does it?

8 MR. JACKSON: Objection, form.

9 A. Yeah, It gives you predictions, certainly.  
10 BY MR. HUTCHINSON:

11 Q. It doesn't give you lifetime facts or  
12 lifetime specifics, does it?

13 MR. JACKSON: Objection, form.

14 A. Every time you use an accelerated test  
15 protocol to get a prediction, it's only a prediction  
16 and you have to follow it up with real life, live  
17 tests to validate.

18 BY MR. HUTCHINSON:

19 Q. And you have to follow it up with real  
20 time aging tests, correct?

21 MR. JACKSON: Objection, form.

22 A. That is correct.

23 BY MR. HUTCHINSON:

24 Q. Doctor, you wouldn't rely on a qualitative

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1 test to determine how long a polymer would retain  
2 its physical properties, would you?

3 MR. JACKSON: Objection, form.

4 A. I would use it for predictive purposes,  
5 yes.

6 BY MR. HUTCHINSON:

7 Q. Doctor, let's move on to the top of Page  
8 2. Under Note 2 it states, "The OIT measurement is  
9 an accelerated thermal-aging test and as such can be  
10 misleading."

11 Did I read that correctly?

12 A. Yes.

13 Q. What does misleading mean?

14 MR. JACKSON: Objection, form.

15 A. What they are trying to say there is, if I  
16 have different materials, say two different  
17 polypropylenes with two different stabilizer  
18 packages, one polypropylene has additive stabilizer  
19 antioxidant A in it and another one has antioxidant  
20 stabilizer package B in it and I run an OIT and I  
21 get different values, that it would be misleading  
22 for me to say that one is better than the other.

23 BY MR. HUTCHINSON:

24 Q. Did you consider this statement before

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1 doing your testing?

2 MR. JACKSON: Objection, form.

3 A. Yes.

4 BY MR. HUTCHINSON:

5 Q. Doctor, one would never expect to use  
6 Prolene in the body at 200 degrees C, would they?

7 A. That's correct.

8 Q. In fact, you would never expect Prolene to  
9 be exposed to a hundred percent nitrogen in vivo,  
10 would you?

11 A. No.

12 Q. You'd never expect Prolene to be exposed  
13 to a hundred percent oxygen in vivo, would you?

14 MR. JACKSON: Objection, form.

15 A. Not pure oxygen. I certainly would expect  
16 it to be exposed to oxidizing species, but not a  
17 hundred percent pure oxygen, no.

18 BY MR. HUTCHINSON:

19 Q. Moving on down on Note 2, last sentence it  
20 says, "Volatile antioxidants may generate poor OIT  
21 results even though they may perform adequately at  
22 the intended use temperature of the finished  
23 product."

24 Did I read that correctly?

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1 level of volatility.

2 If it comes through in less than 10  
3 minutes, it is volatile. If it takes 20 minutes to  
4 come off the GC column, you know that at  
5 200 degrees, it is not volatile. And I did the same  
6 thing for Santonox R.

7 Q. Doctor, did you account for the volatility  
8 of any other additives contained in Prolene?

9 A. No, I was focused on the antioxidant  
10 species.

11 Q. Did you focus any on Procol LA-10?

12 A. No.

13 Q. Did you ever focus on calcium stearate?

14 A. No. Those are lubricants, not  
15 antioxidants.

16 Q. Doctor, the intended use temperature of  
17 the finished product, what is the intended use  
18 temperature of the finished product?

19 MR. JACKSON: Objection, form.

20 A. 37 degrees C or 98.6 Fahrenheit.

21 BY MR. HUTCHINSON:

22 Q. It is not 200 degrees C, is it?

23 A. No.

24 Q. Doctor, moving on down to Note 3, "There



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1 is no accepted sampling procedure, nor have any  
2 definitive relationships been established for  
3 comparing OIT values on field samples to those on  
4 unused products. Hence, the use of such values for  
5 determining life expectancy is uncertain and  
6 subjective."

7 Did I read that correctly?

8 A. Absolutely, yes.

9 Q. Doctor, what would the field sample be in  
10 this particular case?

11 A. The Prolene mesh.

12 Q. It would be an explant, correct?

13 MR. JACKSON: Objection, form.

14 A. No, it's a virgin, unused implant.

15 BY MR. HUTCHINSON:

16 Q. That's what you consider to be a field  
17 sample?

18 A. Yes.

19 Q. What's the difference between a virgin,  
20 unused piece of Prolene and an unused product?

21 MR. JACKSON: Objection, form.

22 A. There is no difference.

23 BY MR. HUTCHINSON:

24 Q. Doctor, the ASTM that you quote says



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1     there have been no definitive relationships  
2     established for comparing values on field samples to  
3     those for unused products.

4             MR. JACKSON: Objection, misstates  
5     witness testimony.

6     BY MR. HUTCHINSON:

7             Q.     That's what the ASTM says, correct?

8             A.     Okay.

9             Q.     And in fact, Doctor, there's been no  
10    definitive relationships established for comparing  
11    the OIT values of explant to mesh that's never been  
12    used in surgery; is that fair?

13            A.     That is fair, yes.

14            Q.     In fact, Doctor, can you stand by your  
15    opinions to a reasonable degree of scientific  
16    certainty, given that the ASTM that you used says  
17    "determining life expectancy is uncertain and  
18    subjective"?

19            MR. JACKSON: Objection, form.

20            A.     I'm sorry, I don't understand that  
21    question. Would you repeat it, please?

22    BY MR. HUTCHINSON:

23            Q.     Can you stand by your opinions, given that  
24    the ASTM that you used says "determining life

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1     expectancy is uncertain and subjective"?

2                 MR. JACKSON:  Objection, form.

3                 A.     What I can say is this, the life  
4     expectancy is uncertain, that's correct.

5     BY MR. HUTCHINSON:

6                 Q.     And the life expectancy is also  
7     subjective, isn't it, sir?

8                 MR. JACKSON:  Objection, form.

9                 A.     All I can say is in a nutshell, this data  
10    shows that the Prolene material will not last  
11    indefinitely in the body.  It is susceptible to  
12    oxidative degradation over time.

13    BY MR. HUTCHINSON:

14                Q.     But the life expectancy is subjective,  
15    isn't it, sir?

16                MR. JACKSON:  Objection, form.

17                A.     It is subject to the conditions in the  
18    body, yes, certainly.

19    BY MR. HUTCHINSON:

20                Q.     It is also subjective according to the  
21    ASTM protocol, correct?

22                A.     It's always subjective, lifetime of any  
23    article is subject to the conditions that the part  
24    is under, exposed to.

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1 Steve Johnson?

2 A. It's called a DSC pan.

3 Q. What is the DSC pan that Steve Johnson  
4 used made out of?

5 A. He told me. It's in the report and I  
6 don't recall offhand.

7 Q. It is in your expert report?

8 A. No, it's in his report to me.

9 Q. Steve Johnson prepared a report and gave  
10 it to you?

11 MR. JACKSON: Objection, form.

12 A. It's data. He gives me the data with a  
13 little note and it tells what the pan is, but I  
14 don't recall offhand what the pan is.

15 BY MR. HUTCHINSON:

16 Q. Where is the data that Steve Johnson gave  
17 you?

18 A. It would be on my computer.

19 Q. It is not included on this flash drive, is  
20 it, sir?

21 A. It probably is.

22 Q. Can you testify under oath that this data  
23 that Steve Johnson gave you is contained on this  
24 flash drive?

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1 MR. JACKSON: Objection, form.

2 A. Not without checking to confirm for sure.  
3 I believe I put it on there.

4 BY MR. HUTCHINSON:

5 Q. Doctor, sitting here today, can you tell  
6 us the type of specimen holder that Steve Johnson  
7 used?

8 A. A DSC pan, and I don't recall what the  
9 metal was.

10 Q. Do you know if Steve Johnson used more  
11 than one specimen holder?

12 A. The little DSC pans are disposable. In  
13 other words, for the OIT test, he uses a specific  
14 type of pan that he knows to be, not influence the  
15 data and that's the type of pan he uses. I just  
16 don't recall offhand what the metal is.

17 Q. Doctor, have you done anything to  
18 determine if the specimen holder that Steve Johnson  
19 used affected the results?

20 MR. JACKSON: Objection, form.

21 A. As I say, he in the past has run tests,  
22 since he runs the OIT for me all the time, to  
23 confirm the OIT test as he runs it is unaffected by  
24 the pan that he uses. It's just I don't recall what



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1 metal it is.

2 BY MR. HUTCHINSON:

3 Q. I understand that, Doctor, but I'm asking  
4 you, have you done anything personally to determine  
5 if the specimen holder that Steve Johnson used  
6 affected the test results?

7 A. I don't run DSC, so technicians do that.

8 Q. Have you done anything, sir, personally to  
9 determine if the specimen holder affected the  
10 results?

11 MR. JACKSON: Objection, asked and  
12 answered.

13 A. As I say, it was done in the past, on past  
14 projects.

15 BY MR. HUTCHINSON:

16 Q. I am talking about this project, sir.  
17 Have you personally done anything to determine if  
18 the specimen holder affected the results, yes or no?

19 MR. JACKSON: Objection, asked and  
20 answered.

21 A. In the sense that I made sure that he is  
22 using his standard pan under the standard operating  
23 procedures for the laboratory as an A2LA certified  
24 laboratory. They are annually audited, all their



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1 MR. JACKSON: Objection, form.

2 A. Because it's not a -- it has to do with  
3 sterile medical device packages, not what's inside.  
4 So it's really not a standard that's directly  
5 applicable to this situation.

6 BY MR. HUTCHINSON:

7 Q. Doctor, fair to say you never did any  
8 real-time aging studies to confirm the accelerated  
9 aging study results that you generated, correct?

10 A. That is correct.

11 Q. All of the studies that you did are  
12 contained in your expert report; is that correct?

13 MR. JACKSON: Objection, form.

14 A. I mean, I mentioned a few minutes ago, I  
15 ran the OIT test under pure oxygen and then  
16 switching from nitrogen to air, and I believe that's  
17 the only deviation that was done that wasn't  
18 included in the report.

19 BY MR. HUTCHINSON:

20 Q. Doctor, turn with me to Page 2.

21 A. Of?

22 Q. Of Exhibit 5 which is ASTM 1980.

23 A. Yes.

24 Q. There on Page 2, note 6.4, this is a

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1 BY MR. HUTCHINSON:

2 Q. "Materials which are not exposed to light  
3 during their normal life could be tested in heat  
4 aging experiments."

5 In fact, that's what you did, correct, a  
6 heat aging experiment, correct, on mesh?

7 MR. JACKSON: Objection, form.

8 A. Yes, I did.

9 BY MR. HUTCHINSON:

10 Q. It goes on to say, "But if temperatures  
11 are used which are considerably higher than the ones  
12 the material is exposed to under normal  
13 circumstances, the danger exists of introducing new  
14 degradation reactions."

15 Did I read that correct?

16 A. Yes, you did.

17 Q. Doctor, did you consider that before you  
18 did your accelerated aging tests?

19 A. Yes.

20 Q. Did you know what de la Rie said about  
21 using higher temperatures?

22 A. Yes.

23 Q. How did you account for that?

24 A. By stating that it is only a rough

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1 approximation and has to be validated with actual  
2 real-time studies because of this possibility.

3 Q. Doctor, did you do any type of calculation  
4 regarding the Arrhenius rate reaction for  
5 polypropylene?

6 MR. JACKSON: Objection, form.

7 A. That has been done in the literature  
8 before.

9 BY MR. HUTCHINSON:

10 Q. I am asking you: Did you do any  
11 calculation for the Arrhenius rate reaction for  
12 polypropylene?

13 MR. JACKSON: Objection, form.

14 A. Not on my data, no, I couldn't, because I  
15 only ran at one temperature. I did not run at  
16 three temperatures. You have to run at three  
17 temperatures to do the Arrhenius calculations.

18 MR. HUTCHINSON: We can take a quick  
19 break.

20 THE VIDEOGRAPHER: We are now off  
21 the video record. The time is 10:01 a.m.

22 (Recess.)

23 THE VIDEOGRAPHER: We are back on  
24 the video record with Tape Number 2. The

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1 selecting material, so they just asked me to  
2 recommend a material for a certain application. And  
3 I considered polypropylene and ruled it out, just  
4 didn't have the right properties for the  
5 application.

6 Q. Doctor, have you ever selected a polymer  
7 that has a lifetime warranty?

8 MR. JACKSON: Objection, form.

9 A. I don't believe so.

10 BY MR. HUTCHINSON:

11 Q. Doctor, would you ever guarantee to the  
12 recipients of these medical devices that you  
13 consulted for, would you ever guarantee to them that  
14 their material would never oxidize?

15 MR. JACKSON: Objection, form.

16 A. No.

17 BY MR. HUTCHINSON:

18 Q. Doctor, on Page 3 of your expert report,  
19 you reference ISOT. That stands for incipient  
20 surface oxidation time; is that correct?

21 A. Yes.

22 Q. Is ISOT in any ASTM standard?

23 A. It is nowhere. That is my own acronym.

24 Q. Doctor, you didn't use a publication to



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1      come up with your own acronym, did you?

2           A.     I did not.

3           Q.     You made it up just for this experiment,  
4      didn't you?

5           MR. JACKSON:   Objection, form.

6           A.     No.

7      BY MR. HUTCHINSON:

8           Q.     Where did you come up with your own  
9      acronym?

10          MR. JACKSON:   Objection, form.

11          A.     As I say, I have been using OIT testing  
12      for years.

13      BY MR. HUTCHINSON:

14          Q.     I want to talk about ISOT.

15          A.     Yes, I know.   And as part of that, I look  
16      at the shape of the OIT curve because normally it is  
17      a nice, smooth transition with two slopes and when  
18      you get the baseline meandering around and doing  
19      strange things, you know that there's something  
20      going on that's not normal.   And so I always, just  
21      for my own thought processes, identify the point to  
22      where something chemically starts to happen and I  
23      call that the incipient oxidation point.

24          Q.     But that's something you made up?



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1           A.    I did, yes.

2           Q.    Doctor, if you look at Page 5, it states,  
3 polypropylene is subject to degradation or weakening  
4 by oxidative agents.

5           A.    Where are you at now?

6           Q.    Page 5.

7           MR. JACKSON: Chad, can you let us  
8 know which paragraph you are on?

9           MR. HUTCHINSON: Yes, I'm sorry.  
10 Second paragraph, second sentence.

11           THE WITNESS: Okay.

12 BY MR. HUTCHINSON:

13           Q.    It states, the "chemical reactions  
14 continue to occur so long as any oxidizing agents,  
15 such as those present in the human body, are  
16 present." Do you see that?

17           A.    Yes.

18           Q.    Doctor, what are the names of the  
19 oxidizing agents?

20           MR. JACKSON: Objection, form.

21           A.    Excuse me?

22           Q.    What are the names of the oxidizing agents  
23 that you reference here?

24           MR. JACKSON: Objection, form.

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1 it affects Prolene?

2 A. I have not done that.

3 Q. Doctor, do you have any idea how many or  
4 what type of -- strike that.

5 Do you have any idea of the amount of  
6 enzymes, oxidizing enzymes that are secreted from  
7 the body?

8 MR. JACKSON: Objection, form.

9 A. I have never measured it, no.

10 BY MR. HUTCHINSON:

11 Q. To your knowledge, has it ever been  
12 quantified?

13 A. I do not know.

14 Q. Doctor, sitting here today, can you  
15 quantify the amount of oxidizing agents that are  
16 produced by the human body?

17 MR. JACKSON: Objection, asked and  
18 answered.

19 A. Are you asking have I done it or could it  
20 be done?

21 BY MR. HUTCHINSON:

22 Q. I am asking, have you done it?

23 A. I have not done it.

24 Q. Do you know the amount of oxidizing agents

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1 produced by the human body?

2 MR. JACKSON: Objection, asked and  
3 answered.

4 A. No.

5 BY MR. HUTCHINSON:

6 Q. Doctor, do you have any opinions regarding  
7 the quantity of oxidizing agents it would take to  
8 oxidize Prolene?

9 A. Well, Prolene is an oxidizable material,  
10 so any oxidant is capable of oxidizing Prolene.

11 Q. My question, sir: Do you have any idea  
12 about the concentration level of oxidizing agents  
13 that it would take to oxidize Prolene?

14 A. Any detectable, measurable amount of an  
15 oxidizing species is capable of oxidizing Prolene.

16 Q. Can you quantify that, Doctor?

17 MR. JACKSON: Objection, form.

18 A. A detectable, I don't know what the  
19 detection limit of a test you want to use, but if it  
20 is detectable, it is capable of oxidizing Prolene.

21 BY MR. HUTCHINSON:

22 Q. What about a micromole, can a micromole  
23 oxidize Prolene?

24 MR. JACKSON: Objection, form.

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1 Q. Let's talk about the chemistry for  
2 Santonox R.

3 MR. JACKSON: Chad, he wasn't  
4 through answering his question. You got  
5 to let him finish.

6 BY MR. HUTCHINSON:

7 Q. Santonox R is designed to remove free  
8 radicals when they are formed, correct?

9 A. I wouldn't say remove, but negate the  
10 effects of free -- interferes with free radical  
11 chain reactions.

12 Q. Doctor, let's look at Page 8 at the top.  
13 You reference the testing you did, the gas  
14 chromatography, mass spectroscopy, did I say that --

15 A. That's correct.

16 Q. Is that the testing that you did?

17 A. Yes.

18 Q. Did you personally do the GS-MC testing?

19 A. GC-MS.

20 Q. GC-MS testing?

21 A. I don't run lab equipment. Trained  
22 technicians run lab equipment. I worked with a  
23 technician to tell him how I wanted the test  
24 performed, yes.



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1 Q. Who did the GC-MS testing, Doctor?

2 A. Steve Johnson.

3 Q. He did it too?

4 A. Yes, he is the technician that does GC-MS  
5 and the OIT test.

6 Q. Which did Steve Johnson do first, did he  
7 do the GC-MS or the DSC testing?

8 MR. JACKSON: Objection, form.

9 A. He did the OIT first and then I wanted to  
10 see if it correlated with the additives so I asked  
11 him to do GC-MS so I could see if there was a  
12 statistical correlation.

13 BY MR. HUTCHINSON:

14 Q. Let's talk about the GC-MS testing that  
15 Steve Johnson did. Did Steve Johnson's GC-MS  
16 experiment follow any standard or published  
17 procedure?

18 A. It followed what's called SOP, standard  
19 operating procedure. Again, all certified  
20 laboratories need SOPs for everything they do.  
21 Those SOPs are audited annually, and he followed  
22 his SOP for GC-MS.

23 Q. Which SOP did Mr. Johnson follow?

24 A. The one for GC-MS in the lab.

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1 Q. But what number?

2 A. I don't -- it's probably in the lab report  
3 he sent me, but I don't have the number memorized.

4 Q. Doctor, did you ever touch the GC-MS  
5 equipment?

6 MR. JACKSON: Objection, form.

7 A. No.

8 BY MR. HUTCHINSON:

9 Q. Did you ever touch the DSC equipment?

10 MR. JACKSON: Objection, form.

11 A. No.

12 BY MR. HUTCHINSON:

13 Q. Have you ever even seen the GC-MS or DSC  
14 equipment?

15 MR. JACKSON: Objection, form.

16 A. Yes, I have.

17 BY MR. HUTCHINSON:

18 Q. At Steve Johnson's lab?

19 A. At Steve Johnson's lab. As a matter of  
20 fact I have watched him in the past run it.

21 Q. But you didn't watch him do this  
22 experiment --

23 A. No.

24 Q. -- that we are here about today?

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1           A.    No, I did not.

2           Q.    Doctor, did Steve Johnson perform any  
3   controls in his GC-MS experiment?

4           A.    Yes.

5           Q.    What were they?

6           A.    He always puts in an internal standard in  
7   the solvent that he extracts, the additives from the  
8   plastic, and that internal standard he looks at the  
9   size of the response and the retention time to make  
10   sure that the equipment is operating. In other  
11   words, it is a known material spiked into the  
12   solvent and if that peak is not right, he knows  
13   there's an issue.

14          Q.    Did that generate data?

15               MR. JACKSON: Chad, you have to let  
16   the witness finish his answer.

17   BY MR. HUTCHINSON:

18          Q.    I'm sorry, Doctor, if I interrupted you.  
19   Did that generate data?

20          A.    What do you mean?

21          Q.    Using the control, when Mr. Johnson used  
22   the control, did it generate any data?

23          A.    Yes.

24          Q.    Where is that data?

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1           A.    It would be in his GC-MS data report.

2           Q.    Is Mr. Johnson's GC-MS data report  
3 included on the flash drive that you gave me before  
4 the deposition?

5           A.    I believe so.

6           Q.    Why wasn't that GC-MS data included in  
7 your expert report?

8           A.    I included just this comment of the  
9 correlation, but I did not include the data in the  
10 report.

11          Q.    But why not? Why didn't you include the  
12 data in your report?

13          A.    I just didn't.

14          Q.    Doctor, did Steve Johnson ever try to  
15 measure the concentration level of DLTDP?

16          A.    Yes.

17          Q.    What was the result of the concentration  
18 level of DLTDP?

19          A.    When he ran the test, he did not see the  
20 DLTDP. He couldn't detect it.

21          Q.    Doctor, have you personally ever tried to  
22 measure the concentration level of DLTDP in Prolene?

23          A.    Through Steve Johnson I have attempted to  
24 do it.



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1 Q. Do you know Dr. Howard Jordi?

2 A. I know there's a Jordi Lab.

3 Q. Do you know if the Jordi Labs ever  
4 detected DLTDP in Prolene?

5 A. I don't know.

6 Q. If Dr. Jordi's lab did detect DLTDP in  
7 Prolene, that would be inconsistent with the results  
8 of your tests, correct?

9 MR. JACKSON: Objection, form.

10 A. No.

11 BY MR. HUTCHINSON:

12 Q. I thought you told me your tests did not  
13 detect DLTDP.

14 A. No, I'm saying that the way the test was  
15 run, it did not detect it. He only saw a peak for  
16 the Santonox R.

17 Q. Doctor, is it your testimony under oath  
18 that the Prolene sample that Mr. Johnson used did  
19 not have any DLTDP in it?

20 A. No, it likely did. It's just the way  
21 that particular test was run, it was  
22 non-detectable. But -- yeah, that's all.

23 Q. It probably wasn't the best test to  
24 determine whether or not DLTDP was in the Prolene?

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1 MR. JACKSON: Objection, form.

2 A. That's correct, yes.

3 BY MR. HUTCHINSON:

4 Q. Doctor, did you do any type of appropriate  
5 testing to determine the level of DLTDP in Prolene?

6 MR. JACKSON: Objection, form.

7 A. Yes, I tried to. I actually had him  
8 experiment with different conditions to try to  
9 detect the DLTDP. He did find a condition where he  
10 was able to see it. It's just not -- so it's there,  
11 it's just not reported in this data.

12 Q. What test did he use to detect DLTDP?

13 A. GC-MS, again. It's just he ran it under  
14 different conditions.

15 Q. Doctor, why is that information not in  
16 your expert report?

17 A. Because the purpose for doing it was to  
18 just make sure that it was there. I wanted to make  
19 sure it was there.

20 Q. And you confirmed it was there?

21 A. I confirmed it was there.

22 Q. Or rather Mr. Johnson confirmed it was  
23 there?

24 MR. JACKSON: Objection, form.

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1 vivo.

2 Q. Doctor, do you know what the weight loss  
3 rate is for DLTDP in vivo?

4 A. That's what I just answered. The only  
5 thing I know is from Dr. Burkley's work.

6 Q. Same question for Santonox R: Do you know  
7 what the weight loss rate is for Santonox R in vivo?

8 A. No.

9 Q. Doctor, do you know what the melting point  
10 is for DLTDP?

11 A. Not offhand.

12 Q. Do you know what the melting point for  
13 Santonox R is?

14 A. Again, not offhand.

15 Q. Doctor, when we talk about the GC-MS  
16 testing, what color was the exemplar that Steve  
17 Johnson tested?

18 A. It's in the lab report he sent me. He  
19 listed the lot number and the color.

20 Q. What color was it?

21 A. I don't recall if it was blue or white.  
22 I'd have to look at the lab report.

23 Q. What temperature was the GC-MS set for?

24 A. It's a program. Its oven temperature is

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1     ramped up over time because these additives, like  
2     if the oven temperature was set at 40 degrees and  
3     you injected the sample, the additive would never  
4     come through the instruments. So you've got to keep  
5     raising the temperature until it comes through.

6           Q.     What temperature was it when the material  
7     began coming through?

8           MR. JACKSON:   Objection, form.

9           A.     I can't tell you precisely. I can tell  
10    you it was over 200 degrees.

11   BY MR. HUTCHINSON:

12          Q.     Was a solvent used by Mr. Johnson with  
13    this GC-MS?

14          A.     Yes.

15          Q.     Do you know what type of solvent Mr.  
16    Johnson used?

17          A.     Methylene chloride.

18          Q.     Do you know what quantity of methylene  
19    chloride that Mr. Johnson used?

20          A.     Again, it is in his lab procedure he sent  
21    me. I don't know the number offhand.

22          Q.     Doctor, you will agree that that solvent  
23    only extracts volatile materials, correct?

24          MR. JACKSON:   Objection, form.



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1 this particular test right here, he couldn't see it.

2 BY MR. HUTCHINSON:

3 Q. What concentration level did Mr. Johnson  
4 find DLTDP in?

5 A. The particular -- I remember numbers,  
6 hundreds of parts per million.

7 Q. Right, but can you quantify the amount of  
8 DLTDP concentration level that Mr. Johnson found?

9 A. I'm sorry, the question again?

10 Q. Can you quantify the concentration level  
11 of the DLTDP that Mr. Johnson found?

12 A. As I said, it was hundreds of parts per  
13 million. I just don't remember the exact number.

14 Q. Did Mr. Johnson ever tell you that exact  
15 number?

16 MR. JACKSON: Objection, form.

17 A. Yes.

18 BY MR. HUTCHINSON:

19 Q. Where would that data be included?

20 A. In the data report.

21 Q. Where is the data report?

22 A. Should be on the flash drive.

23 Q. Look at Page 9 for me, please, of your  
24 expert report under Summary, Number 2.

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1 Q. Outside the literature, have you ever seen  
2 personally a Prolene explant that has become  
3 brittled?

4 A. No.

5 Q. Or degraded?

6 A. No.

7 Q. Or oxidized?

8 A. No.

9 Q. Or lost physical properties?

10 MR. JACKSON: Objection, form.

11 A. Just in pictures in the literature.

12 BY MR. HUTCHINSON:

13 Q. In fact, you have never done any testing  
14 or analysis on the degradation of Prolene before  
15 your involvement in this case; is that correct?

16 MR. JACKSON: Objection, asked and  
17 answered.

18 A. Before involvement in the case, no.

19 BY MR. HUTCHINSON:

20 Q. Am I correct?

21 A. That's correct.

22 Q. Thank you. Doctor, you were designated  
23 in -- let's look at Exhibit 1 for me, please, it is  
24 the notice of deposition.

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1 the last ten years on explanted meshes that show  
2 degradation.

3 Q. Doctor, are you aware of any clinical data  
4 that shows degradation is clinically significant?

5 MR. JACKSON: Objection, form.

6 A. Clinically, I can't equate to that,  
7 clinically significant.

8 BY MR. HUTCHINSON:

9 Q. Doctor, are you aware of any clinical data  
10 that shows degradation causes clinical harm?

11 A. Again, since I'm not a medical doctor, I  
12 can't equate the clinical.

13 Q. Are you aware of any data that shows  
14 degradation causes harm in women?

15 A. Any data?

16 Q. As a scientist.

17 A. Other than reading the scientific  
18 literature that I've talked about on explants.

19 Q. Doctor, have you concluded that Prolene is  
20 toxic?

21 MR. JACKSON: Objection, form.

22 A. I know from reading the MSDS sheets on the  
23 different additives in Prolene, I know that the  
24 colorant, the copper phthalocyanine pigment is

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## C E R T I F I C A T E

G E O R G I A :

H E N R Y C O U N T Y :

I hereby certify that the foregoing deposition was reported, as stated in the caption, and the questions and answers thereto were reduced to the written page under my direction; that the foregoing pages 1 through 168 represent a true and correct transcript of the evidence given. I further certify that I am not in any way financially interested in the result of said case.

Pursuant to Rules and Regulations of the Board of Court Reporting of the Judicial Council of Georgia, I make the following disclosure:

I am a Georgia Certified Court Reporter. I am here as an independent contractor for Golkow Global Litigation Services.

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This, the 9th day of March, 2016.

---

MAXYNE BURSKY, CCR-2547